IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), **Plaintiffs,** **v.** **MIKE HILGERS, in his official capacity as ATTORNEY GENERAL OF THE STATE OF NEBRASKA,** **Defendant.**	**Case No. 4:25-cv-03089** **SUPPLEMENTAL BRIEF IN RESPONSE TO PLAINTIFF ABBVIE PRODUCTS LLC, et. al., AMENDED COMPLAINT**

Defendant Michael T. Hilgers, Attorney General of Nebraska, submits this Supplemental Brief in Response to Plaintiffs AbbVie Products, LLC, *et. al.* ("Plaintiffs') Amended Complaint. Filing No. 45.[1]

[1] On August 25, 2025, the Court consolidated this case with *Pharmaceutical Research and Manufacturers of America v. Hilgers*, No. 4:25-cv-3163 (D. Neb.). *See* Filing No. 44. This Supplemental Brief is submitted as permitted by the Court's consolidation order. Filing No. 44. References to "Plaintiffs" in this brief refer only to the plaintiffs in the "Lead Case," No. 4:25-cv-3163—that is, Abbvie et al.—not the plaintiff in the "Member Case," No. 4:25-cv-3163. As reflected in the Court's Consolidation Order, Attorney General Hilgers reserves the right to file a supplemental reply brief responding to any new arguments presented by the plaintiff in the Member Case once that plaintiff files a response in opposition to the pending motion to dismiss. *See* Filing No. 44.

INTRODUCTION

On August 25, 2025, Plaintiffs filed their Amended Complaint. Filing No. 45. Attorney General Hilgers did not object to the amendment. *See* Filing No. 43. The most significant change made by the Amended Complaint is the addition of allegations regarding the Inflation Reduction Act ("IRA"). *See* Filing No. 45 at ¶¶ 108–19, 157–64. After amendment, Plaintiffs now allege (in addition to their previous preemption arguments) that L.B. 168 is preempted by the IRA because Nebraska's law "interferes with [Plaintiffs'] ability to participate" in a "Pilot Rebate Program" established by the IRA, which, they allege, both "assumes" and "explicitly contemplates" that pharmaceutical manufacturers may "collect claims data under the 340B Program." *Id*. at ¶¶ 162, 164.

Plaintiffs' new preemption claim fails for many of the same reasons already set forth in the Attorney General's prior briefing. *See* Filing No. 27 at 20–28; Filing No. 37 at 7–14. This brief will not rehash those arguments at length; they are incorporated by reference and reasserted here. Only a few additional points, specifically tailored to Plaintiffs' new IRA preemption claim Amended Complaint, are advanced below.

Plaintiffs' Amended Complaint should be dismissed.

ARGUMENT

I. L.B. 168 Is Not Preempted by the IRA.

Plaintiffs' new preemption claim is best understood as a claim of "conflict" or "obstacle" preemption. Conflict preemption "requires the identification of [an] 'actual conflict' between a state and federal law." Filing No. 27 at 22–23 (quoting *Geier v.*

Am. Honda Motor Co., 529 U.S. 861, 884 (2000)); *see also Eng. v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990) ("pre-emption is ordinarily not to be implied absent an 'actual conflict.'"). "[C]onflict pre-emption exists where compliance with both state and federal law is impossible, or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1140 (8th Cir. 2024) (internal quotation mark omitted). No such conflict exists here.

A.

At the outset, there is no conflict because the IRA pilot program that lies at the heart of Plaintiffs' claim is entirely voluntary. *See* 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed Reg. 38165 (August 7, 2025) (inviting "certain drug manufacturers" to "apply for participation in a *voluntary* 340B Rebate Model Pilot Program") (emphasis added). A viable claim of conflict preemption requires a state law that conflicts with a "federal regulatory *mandate*[]." *Geier*, 529 U.S. at 871 (emphasis added). A voluntary pilot program is obviously not a federal mandate. Accordingly, it is not impossible for Plaintiffs to *comply* with both federal law (the IRA) and state law (L.B. 168) because the IRA pilot program does not *impose anything*—on Plaintiffs or anyone else.

Nor does there exist a legitimate obstacle to the "to the accomplishment and execution" of the objectives of Congress. *McClain*, 95 F.4th at 1140. The stated purpose of the pilot rebate program is to "inform . . . consideration of any future 340B rebate models consistent with the 340B statute." 90 Fed Reg. at 38165. Necessarily

then, the pilot program is designed to work in tandem with the 340B scheme. And as the Attorney General has already explained, so is L.B. 168. *See* Filing No. 27 at 3; *see also* McClain, 95 F.4th at 1143 ("the 340B Program is not so pervasive . . . that Congress left no room for the States to supplement it") (internal quotation marks omitted). Thus, both the pilot program and L.B. 168 are aimed at effectuating the objectives of Congress as reflected in the 340B statutory scheme. Those objectives include the subsidization of "other services provided by" 340B covered entities, most notably the "a wide range of medical services in low-income and rural communities" including "treatments for cancer, mental health issues, opioid addiction, and diabetes" that those covered entities provide. *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 730–31 (2022); *see also* Brief in Support of Motion to Dismiss, *AstraZeneca Pharmaceuticals LP, v. Hilgers*, No. 4:25-cv-3128, Filing No. 22 at 3 & n.1 (D. Neb. July 8, 2025). Plaintiffs do not explain why a *voluntary* pilot program should be seen as reflective of the will of Congress and L.B. 168 should not. Nor have they explained why that pilot program should be elevated above a state law that is designed to further a central objective of the federal 340B program and ensure that objective is not unilaterally frustrated by overly restrictive delivery and data collection policies.

B.

Plaintiffs' new preemption claim assumes that L.B. 168 "prevents [drug manufacturers] from requesting and obtaining" "claims and utilization data from covered entities." Filing No. 45 at ¶¶ 163, 164. Not so. L.B. 168 prohibits drug manufacturers from *requiring* that such data be provided as *a condition precedent* to

the acquisition or delivery of 340B drugs to a covered entity authorized to acquire or receive them. *See* L.B. 168, § 3(2) 109th Leg., 1st sess. (2025) (enacted). But forbidding the imposition of onerous delivery or acquisition *conditions* is not the same thing as forbidding all *requests for* or otherwise preventing *the collection of* claim or utilization data. "L.B. 168 does not outright prohibit manufacturers from *collecting* or *demanding* data from covered entities related to 340B drugs." Filing No. 27 at 26.

This distinction dooms Plaintiffs' preemption claim. Indeed, nothing stops Plaintiffs from applying to participate in the pilot program and then, assuming they are accepted, asking covered entities to provide the "claims data" that the pilot program is designed to collect. All L.B. 168 prevents drug manufacturers from doing is couching a "request" in the form of a "condition for allowing the acquisition of any 340B drug by or delivery of any 340B drug." L.B. 168, § 3(2). In short, manufacturers can *ask* covered entities (and/or contract pharmacies) to provide claims data; what they cannot do is attempt to *coerce* covered entities or contract pharmacies to provide it via onerous acquisition or delivery conditions. *See* Filing No. 27 at 26 ("L.B 168 forbids a manufacturer from telling a covered entity 'hand over your data or you do not get 34B drugs[.]'")

This reality illustrates another reason why there is no conflict preemption here. A pilot program participant *can* comply with both state and federal law. So long as the manufacturer seeks and/or collects the claim data in question in a permissible

way, that is, *without* imposing the sort of coercive data collection conditions that L.B. 168 forbids, there is no state-law barrier to the collection of that data.[2]

C.

As discussed above, because the pilot program Plaintiffs seek to participate in is voluntary, there is no conflict between a federal *mandate* and Nebraska law. But to the extent Plaintiffs allege that the pilot program creates some *affirmative right* to collect claim data, *see* Filing No. 45 at ¶ 162, there is still no preemption problem. The reason is simple—if federal law somehow *requires* that data be collected, L.B. 168 does not preclude its collection. Simply put, "L.B. 168 does not prohibit manufacturers from obtaining data *necessary* to comply with federal law." Filing No. 27 at 26. This flows straight from L.B. 168's text: Data collection conditions are impermissible "unless such data is required by federal law." L.B. 168, § 3(2).

It is hard to see how voluntary participation in a limited pilot program could result in a *requirement* that some data be collected. But assuming there were such a requirement, L.B. 168's savings clause would obviate any conflict between Nebraska and federal law. Accordingly, Plaintiffs' new preemption claim necessarily fails.

[2] Responding in advance to Plaintiffs' inevitable rejoinder about recalcitrant covered entities, such practical concerns ring hollow in the context of a pilot program designed to obtain "stakeholder feedback" and "better understand the merits and shortcomings of the rebate model." 90 Fed Reg. at 38165. If participating manufacturers who seek claims data in a non-coercive way are consistently stonewalled by covered entities and/or their contract pharmacy partners, that information may spur the federal executive branch (HHS and HSRA) to increase the frequency of 340B audits or spur Congress to amend the statutory framework underlying the 340B scheme. Conversely, manufacturers may discover the can obtain the data they need without imposing onerous acquisition or delivery conditions. Either way, the pilot program will provide the federal government with useful data, which is the *purpose* of a pilot program.

CONCLUSION

For all the reasons set forth above, as well as for those arguments already presented in the pending motion to dismiss and associated briefing, *see* Filing Nos. 27 and 37, Plaintiffs' Amended Complaint should be dismissed.

Dated: September 2, 2025

Respectfully submitted.

MICHAEL T. HILGERS (#24483)
Attorney General of Nebraska

Nebraska Department of Justice
1445 K Street, Room 2115
Lincoln, Nebraska 68508
Tel.: (402) 471-2683
Fax: (402) 471-3297

/s/ ZACHARY A. VIGLIANCO (#27825)
Principal Deputy Solicitor General

JENNIFER A. HUXOLL (#20406)
Assistant Attorney General
Civil Litigation Bureau Chief

LINCOLN J. KORELL (#26951)
Assistant Solicitor General
TYRONE FAHIE (#28125)
Assistant Attorney General

Counsel for Defendant

CERTIFICATE OF COMPLIANCE

Pursuant to NE. Civ. R. 7.1(d), the undersigned hereby certifies that the foregoing principal brief contains 1,670 words (including the caption, headings, footnotes, and quotations) in compliance with said rule. The undersigned utilized the word count function of Microsoft Word for Microsoft Office 365.

/s/ ZACHARY A. VIGLIANCO (#27825)
Zachary A. Viglianco
Deputy Solicitor General